

SUMMARY OF CLAIMS

Claims 31-33, 37, 39-45, 47, 55-76 are pending. Claims 74-76 are new. No new matter has been added.

REMARKS

Applicant respectfully requests entry of the amendment of the specification as described above. The amendment is a true copy of disclosure from U.S. Provisional Application No. 60/265,214 and incorporates no new matter. The original disclosure can be found on page 13 of the specification of Provisional Application No. 60/265,214 at paragraph labeled Number 6. The present application properly claims the benefit of the clearly identified U.S. Provisional Application 60/265,214, and has properly incorporated by reference the disclosure therein in its entirety (see page 160, lines 21-25).

Applicant respectfully requests entry of new independent claims 74-76. Applicant requests entry of these claims to preserve his rights. Applicant respectfully suggests that a Restriction Requirement be made to properly pursue these patentably distinct independent claims in one or more Divisional applications.

Claim Rejections – Obviousness-type double patenting

The Examiner has provisionally rejected claims 31-33, 37, 39-45, 47, 55-73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 11/738,967.

As the above rejection over copending Application No. 11/738,967 is a provisional rejection, Applicant will provide a terminal disclaimer when patentably indistinct claims in this case and Application No. 11/738,967 have been allowed.

In addition, the Examiner has provisionally rejected claims 31-33, 37, 39-45, 47, 55-73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-44 of copending Application No. 11/270,064.

As the above rejection over copending Application No. 11/270,064 is a provisional rejection, Applicant will provide a terminal disclaimer when patentably indistinct claims in this case and Application No. 11/270,064 have been allowed.

Further, the Examiner has provisionally rejected claims 31-33, 37, 39-45, 47, 55-73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 20-69 of copending Application No. 11/125,853.

As the above rejection over copending Application No. 11/125,853 is a provisional rejection, Applicant will provide a terminal disclaimer when patentably indistinct claims in this case and Application No. 11/125,853 have been allowed.

The Examiner has provisionally rejected claims 31-33, 37, 39-45, 47, 55-73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent 6,996,261.

Applicant will provide a terminal disclaimer upon the Examiner finding allowable matter.

Claim Rejections – 35 USC § 103

The Examiner has rejected claims 31, 37, 39-45, 47, 55-73 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,995,857 Toomim et al (hereinafter Toomim).

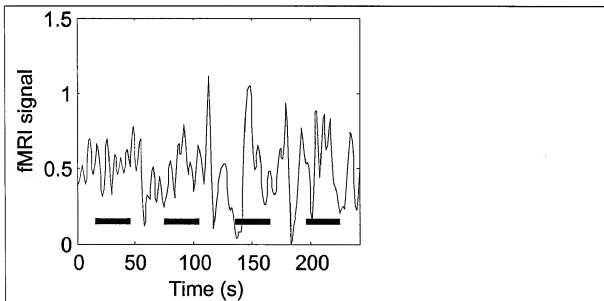
The Examiner alleges that Toomim discloses using radio frequency excitation, such as used in MRI and providing feedback to a patient, and that Toomim further discloses that it is known to use fMRI to measure blood flow in the brain. Based upon that disclosure, the Examiner alleges that it would be obvious to one of skill in the art to have used fMRI in the method of Toomim to provide blood flow information in areas of the brain and communicate feedback and information to a subject suffering from a mental disorder in real time based on measured/determined functional brain activity in a region of interest (such as within the cerebral cortex). Applicant requests reconsideration.

The invention is not obvious because Toomin's disclosure of using fMRI to measure blood flow in the brain is not enabling. Therefore a *prima facie* case of obviousness has not been established.

In fact, what Toomim discloses is that fMRI measurements may eventually become useful for biofeedback (See col. 1, line 44). Therefore, he acknowledges that his invention is not enabled for fMRI measurement. Additionally, Toomin's disclosure of the use of fMRI measurement of blood flow in the brain is not enabling to a person of skill in the art at the time of the present invention for the following reasons.

First, at the time of the present invention, it was not clear that the information provided by fMRI was of high enough quality to contain useful information to serve as the basis for guiding the tasks of a subject.

The figure below, generated by Applicant from the brain of a single subject on a single trial, shows how noisy an rtfMRI signal can be:



This figure shows the timecourse of fMRI activation measured each second over four minutes from a region of interest in the somatomotor cortex in a single subject, prior to rtfMRI-based training. During periods shown with the heavy black bars, the subject was instructed to try to increase the activation measured from the target region of interest. As one can see, this signal is noisy. The signal from times of increased activation are difficult to distinguish from the signal

from lower activation. It was not clear before the invention was made that a subject could use such a signal successfully to learn to control their cognitive processes, such as to learn to control activation in this brain region of interest using cognitive strategies. The fact that it can be done is a surprising result that supports Applicant's contention that the invention was not obvious.

Second it also was not clear at the time of the present invention, that information about brain activity produced by fMRI could be successfully used to guide a cognitive task of a subject who received such information. This type of information is qualitatively different than the signals collected by Toomim and, therefore, there is no basis for comparison or extrapolation.

Third, in reference to claim 67, it was not obvious at the time of the present invention, whether the hemodynamic delay inherent in the brain's blood flow signals would make guiding the cognitive process of a subject using substantially real time fMRI impossible. There is an inherent delay of about 3-5s from the time of neural activation to the time that the fMRI signal shows a meaningful increase. Given that guiding signals are ideally closely time-locked, it was therefore not obvious whether an fMRI signal could be meaningfully used to guide the cognitive processes of subjects. It could have simply been confusing to them.

In summary, Toomim gave no direction to solve these problems and there was no knowledge in the field at the time of the present invention that would supply that lack. For all of these reasons, Toomim's disclosure does not teach one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation (See *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Therefore, Toomim's disclosure is not enabling and the present invention is not rendered obvious by it.

Additionally, the invention is not obvious because if one of skill in the art were to take the disclosure of Toomim and modify it, at the time of the present invention, there would be no reasonable expectation of success.

Applicant wishes to recall the Examiner's attention to two declarations by experts in the field stating that there was not a reasonable expectation of success of the invention, one by Dr. John Gabrieli and one by Dr. Alison Adcock, filed under 35 CFR 1.132 on 7/19/07 and 9/26/07, respectively. Both based their opinions on the nature of fMRI, the kind of information it

produces, and why they believed at the time that such information would likely not be useful for training a subject to control activity in localized brain regions. These experts support Applicant's contention that because neuroimaging data is variable ("noisy"), involves time delays and might not be readily interpreted by a subject, it was not clear at the time of invention that persons could use information communicated to them, based on the measured activity, to guide a cognitive task. Significantly, these opinions do not rely primarily on whether or not there was a suggestion to combine references, but whether there was a reasonable expectation of success that the invention would work based on the knowledge of fMRI at the time.

Applicant respectfully rebuts the Examiner's contention that the declarations merely provide opinion without any evidence produced. Each declarant refers to expert knowledge of two overlapping technical fields, the state of the art at the time, and reasons based on their respective specific research as to why such an invention was indeed not an obvious method at the time of invention. (Please see Declaration of John Gabrieli, page 2 paragraph 2 to page 6, paragraph 1, and Declaration of Alison Adcock, page 2 paragraph 3.) Therefore, Applicant respectfully requests the Examiner to give these declarations their due weight in considering the unobviousness of this invention, and withdraw the rejection.

For all of the above reasons, a *prima facie* case of obviousness can not be established and Applicant respectfully requests withdrawal of the rejection.

The Examiner has rejected claims 32-33 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,995,857, Toomim et al (hereinafter Toomim) in view of U.S. Patent No. 5844241, Liu et al (hereinafter Liu).

The Examiner alleges that Toomim discloses measuring brain activity using fMRI and providing feedback to a patient and that Liu generally demonstrates that voxel sizes less than 1X1X1cm for common imaging modalities are well known. Applicant requests reconsideration.

The disclosure in Toomim is not enabling. Toomim discloses that fMRI measurements may eventually become useful for biofeedback (See col. 1, line 44). Therefore, he acknowledges that his invention is not enabled for fMRI measurement. Toomim's disclosure of the use of

fMRI measurement of blood flow in the brain is not enabling to one of skill in the art at the time of the present invention, because it was not known whether fMRI signals were of high enough quality to be used or whether such information could be used by a subject to guide a cognitive task. Liu does not correct this defect. There is no disclosure in Toomin and/or Liu to enable one of skill to modify the references; the present invention is not made obvious by these references. Further, claims 32 and 33 are dependent from claim 31, which base claim is not rejected over Toomim in view of Liu under 35 U.S.C. 103(a). Therefore a *prima facie* case of obviousness can not be established and Applicant respectfully requests withdrawal of this rejection.

The Examiner has rejected claims 31, 37, 39-45, 47, 55-73 under 35 U.S.C. 103(a) as being unpatentable over Voyvodic "Real Time fMRI Paradigm Control" (hereinafter Voyvodic) in view of U.S. Patent No. 5,995,857 Toomim et al (hereinafter Toomim).

The Examiner alleges that Voyvodic discloses obtaining high-resolution fMRI images and that Toomim discloses measuring brain activity using fMRI and providing feedback to a patient. Applicant requests reconsideration.

The invention is not obvious because if one of skill were to take the disclosure of Voyvodic of obtaining fMRI measurements and the suggestion within Toomim that fMRI measurements may eventually become useful for biofeedback (See col. 1, line 44), the disclosure in the references would not enable the person of skill at the time of the present invention. Therefore a *prima facie* case of obviousness is not established.

The above discussion concluding that the Toomim reference does not have an enabling disclosure for a person of ordinary skill at the time of the present invention applies equally to Voyvodic. In neither case, is there any disclosure which would solve the problem of noisy signal and whether the subject could actually use the communicated information to guide a cognitive task, which, as discussed above was not known in the field at the time of the present invention. For all of these reasons, Voyvodic's and Toomim's disclosures are not enabling to one of skill in the art, and thus the present invention is not rendered obvious by the combination of Voyvodic and Toomim.

Additionally, the invention is not obvious because if one of skill in the art were to take the disclosure of Voyvodic in view of Toomim and modify it, there would be no reasonable expectation of success at the time of the present invention.

Again, Applicant requests that the Examiner reconsider the two declarations by experts in the field, from Dr. John Gabrieli and Dr. Alison Adcock, filed under 35 CFR 1.132 on 7/19/07 and 9/26/07, respectively. In particular the Declaration of John Gabrieli (page 2 paragraph 2 to page 6, paragraph 1) discusses the invention of Voyvodic and the state of the art at the time of invention, and give a number of reasons as to why no one at the time of invention would have a reasonable expectation of success in arriving at the present invention. These reasons include the “noisiness” of the data obtained, potential inability of a subject to use the data to guide a cognitive task, and whether the data would actually be useful to a subject in their attempts to guide a cognitive task. Therefore, Applicant respectfully requests the Examiner to give these declarations their due weight in considering the unobviousness of this invention.

Based on the foregoing, neither reference provides any suggestion that would enable one of skill in the art at the time of the invention to arrive at the present invention, without relying on the teachings herein. A *prima facie* case of obviousness can not be established and Applicant respectfully requests withdrawal of the rejection.

CONCLUSION

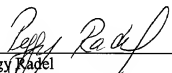
In light of the remarks and amendments set forth above, Applicant believes that the claims are in condition for allowance. Applicant respectfully solicits the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any fees that may be required in connection with this submission, including petition fees and extension of time fees, and to credit any overpayments to Deposit Account No. 23-2415 (Attorney Docket No. 27969-702).

Respectfully submitted,

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